Supreme Court, U.S.
FILED
SEP 25 1986
JOSEPH F. SPANIOL, JR.
CLERK

86-513

No.

IN THE

Supreme Court of the United States

OCTOBER TERM, 1986

ORTHO PHARMACEUTICAL CORPORATION,

Petitioner,

—v.—

KATIE LAUREL WELLS (infant), BY HER MOTHER AND NEXT FRIEND, MARY MAIHAFER, AND FATHER, GARY S. WELLS,

and

MARY MAIHAFER (Individually),

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

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QUESTIONS PRESENTED

1. Whether the Eleventh Circuit improperly applied the clearly erroneous standard of review, and created a new standard for "scientific" cases, in affirming a judgment based on subjective expert opinions contradicted by the objective, scientific evidence?

2. Should this Court resolve the conflict with the other circuits created by misapplication of this standard by the Eleventh Circuit as well as the District of Columbia Circuit (*Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 105 S. Ct. 545 (1984)) which permits a federal appeals court in effect to avoid reviewing complex questions of scientific causation by taking any expert's testimony at face value?

3. Whether this Court should articulate a standard of review to be applied in cases hinging on complex scientific testimony so as to settle an important question of federal law and safeguard the integrity of the factfinding process?

LIST OF PARTIES TO APPEAL TO THE ELEVENTH CIRCUIT COURT OF APPEALS

The names of all the parties to the Appeal to the Eleventh Circuit Court of Appeals are provided in the caption to this Petition. Sup. Ct. R. 21.1(b). Ortho Pharmaceutical Corporation is a wholly owned subsidiary of Johnson & Johnson. Pursuant to Rule 28.1, the following are all of the affiliates of Johnson & Johnson, other than wholly owned subsidiaries:

American Biomaterials Corp.
Cambridge BioScience, Inc.
ens Biologicals, Inc.
Enzo Biochem, Inc.
Immunomedics, Inc.
Thoratec Laboratories Corp.

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OPINIONS BELOW

The orders of the Court of Appeals in this matter dated June 27, 1986 denying the cross-petitions for rehearing of the parties are annexed hereto at pp. A-203-08 of Appendix A. The opinion of the Court of Appeals dated May 6, 1986 affirming in part and modifying in part the judgment of the district court is reported at 788 F.2d 741, and annexed hereto beginning at p. A-1 of Appendix A. The opinion of the district court is reported at 615 F. Supp. 262, and annexed hereto at p. A-29 of Appendix A.

JURISDICTION

This Court has jurisdiction to review the opinion of the Court of Appeals under 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

Rule 52(a), Federal Rules of Civil Procedure:

> Rule 52. Findings by the Court
>
> (a) Effect. In all actions tried upon the facts without a jury or with an advisory jury, the court shall find the facts specially and state separately its conclusions of law thereon, and judgment shall be entered pursuant to Rule 58; and in granting or refusing interlocutory injunctions the court shall similarly set forth the findings of fact and conclusions of law which constitute the grounds of its action. Requests for findings are not necessary for purposes of review. Findings of fact, whether based on oral or documentary evidence, shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses. The findings of a master, to the extent that the court adopts them, shall be considered as the findings of the court. It will be sufficient if the findings of fact and conclusions of law are stated orally and recorded in open court following the close of the evidence or appear in an opinion or memorandum of decision filed by the court. Findings of fact and conclusions of law are unnecessary on decisions of motions under Rules 12 or 56 or any other motion except as provided in Rule 41(b).

STATEMENT OF THE CASE

With the exception of the plaintiffs' experts in this case, no scientist has ever publicly expressed the opinion that vaginal spermicides cause birth defects. Prominent researchers associated with the National Institutes of Health ("NIH"), the Centers for Disease Control ("CDC") and Harvard University, among others, have found no credible scientific evidence of an association between spermicides and birth defects. Likewise, two advisory panels of leading scientists appointed by the Federal Food and Drug Administration ("FDA") reached the same conclusion on all the available studies and decided that a warning of such risks is not warranted by the scientific evidence.

The plaintiffs' experts, relying on their idiosyncratic interpretations of four of the twenty-three scientific studies in evidence, opined otherwise. Both courts below recognized the inherently subjective nature of this opinion evidence but nevertheless found for plaintiffs. The trial court had to concede, however, that the evidence revealed only "a *possible* link between spermicides and birth defects." 615 F. Supp. at 292 (emphasis added), and indeed "found the studies to be *inconclusive* on the ultimate issue of whether the Product caused Katie Wells' birth defects." *Id.* (emphasis added; footnote omitted). Similarly, the Eleventh Circuit affirmed on the rationale that the product "might cause birth defects." *Wells*, 788 F.2d at 746.

Ortho respectfully submits that an objective review of these studies, as well as other publications relied upon by plaintiffs' experts, plainly reveals a complete lack of objective evidence proving causation. Complete copies of these materials have been lodged with the Court.

A. The Nature Of The Proceedings And The Disposition Below

Katie Wells was born in 1981 with a cleft lip, nostril deformity, deformity of her right hand, the complete lack of a left arm with only partial development of her left clavicle and shoulder, and hypoplasia of her right optic nerve. T 11.[1]

Her parents instituted this action against Ortho for, among other things, "the negligent failure to warn" that Ortho-Gynol might cause birth defects.

After a two-week trial, the district court (Judge Shoob) sitting without a jury found that plaintiffs had proven to a reasonable degree of medical certainty that Katie Wells' limb anomalies had been caused by the spermicide, but found otherwise with respect to her cleft lip and right optic nerve injury. T 1878-79. Judge Shoob also found that Ortho knew or should have known that its product might cause birth defects. T 1879; Re 185-86. Accordingly, he held Ortho liable to plaintiffs and awarded them damages in the total amount of $5.1 million, reduced on appeal to $4,736,030.

B. The Regulatory History Of Ortho-Gynol

Ortho-Gynol is a vaginal spermicide containing one active ingredient, "octoxynol," which is a non-ionic surfactant.[2] Ortho has been marketing this product since around 1950. T 1004-05; T 1007. The spermicide is sold as an over-the-counter ("OTC") drug for use with a diaphragm.

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1 Citations to "T ____" herein refer to the trial transcript; "Re ____ refers to record excerpts prepared by Ortho for the Court; and Aa ____ refers to the Appellant's Appendix below.

2 A surfactant is "a surface-active agent." The term "includes substances commonly referred to as wetting agents, surface tension depressants, detergents, dispersing agents [and] emulsifiers." *Stedman's Medical Dictionary* 1373 (24th ed. 1982). A non-ionic surfactant spermicide breaks down the sperm cell membrane. Once the outer membrane separates, the cell disperses its substance and ceases to function. T 177-78; *Population Reports*, "New Developments in Vaginal Contraception," 12(1):158 (Johns Hopkins Univ., Jan.-Feb. 1984) ("*Population Reports 1984*") (Aa 352, 356).

In the early 1970's, the Federal Food and Drug Administration ("FDA") established several expert advisory panels to review the "safety and efficacy" of all OTC drugs. *See* T 1057-58; 21 C.F.R. §§ 330.10 and 330.12; 37 Fed. Reg. 9,464, 9,466 (1972). The panel designated to review OTC contraceptives, including spermicides, first met on August 2, 1973. T 1061; 45 Fed. Reg. 82,014-15 (1980) (Aa 257). After a five-year investigation, including a worldwide literature search, active solicitation and consultation with numerous scientific and medical experts, T 1016; T 1062-71; 45 Fed. Reg. 82,015-16 (1980) (Aa 257-58); T 1012-14, this OTC panel submitted its final report to the FDA concerning OTC vaginal contraceptive drug products. *See* 45 Fed. Reg. 82,014-49 (1980) (Aa 255-91). The panel found, "without question," that vaginal contraceptives like Ortho-Gynol, which contain non-ionic surfactants, are "safe and effective for over-the-counter use." T 1083-84; 45 Fed. Reg. 82,014, 82,028-83,031 (1980) (Aa 270-73).

In November 1983, the FDA requested that one of its standing committees, the Fertility and Maternal Health Drugs Advisory Committee (the "FMHDAC"), evaluate "the safety of vaginal spermicides." T 1216-17; 48 Fed. Reg. 51,533 (1983). After considering the evidence, which included all of the available studies, the FMHDAC unanimously found that:

> [T]he preponderance of the weight of the currently available evidence indicates no association between the maternal spermicide exposure and an increased rate of abortions or congenital malformations.

Transcript of FMHDAC hearing (Aa 620-21).

C. Scientific Data Before The Trial Court

1) *Plaintiffs' Epidemiological Studies*

Thirteen epidemiological studies[3] were entered in evidence. None of the thirteen studies demonstrated an association between spermicide use and limb defects.[4] The trial court singled out two of these studies, Oechsli (Aa 6) and Smith (Aa 27), to support the finding that the product caused the birth defects involved here. Even these studies, however, demonstrate a critical lack of foundation for the findings of causation by the trial court.

Oechsli studied a group of women and utilized data gathered between 1959 and 1966, a time when some spermicides contained the mercury derivative, PMA, later withdrawn from the market because of an FDA finding of toxicity. Aa 9; T 179-80; T 670; T 757-58; T 890. This in and of itself prevents legitimate inferences from being drawn as to the spermicides presently in use. Oechsli reported no association between spermicide use and limb defects—the malformation involved here. The data yielded an association that was barely statistically significant between spermicide use and certain congenital heart defects among children of white women. The chances that this association was a fluke were heightened by the lack of any similar association among black women or among women as a whole.[5]

Inherent in the design of retrospective studies, such as those involved here, is the limitation that they can only show an

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3 Epidemiology is the medical science dealing with the relationships of the various factors which determine the frequencies and distribution of certain diseases and conditions in human populations.

4 Jicks (1981), the sole study that contained any data showing an association between spermicide use and birth defects, by its own terms lacked any real probative value. Jick himself noted that fundamental problems with his study "raises doubt" as to whether the association was real. Aa 36. The more glaring deficiencies are discussed *infra* at page 8.

5 The inability to infer causation from Oechsli's data is obvious, particularly in view of the fact that the data yielded a finding that black women who used spermicides had *lower* rates of birth defects. Aa 14.

association between two events and not a cause and effect relationship. There have been many examples of statistically significant associations which are undeniedly not cause and effect associations, such as Down's Syndrome and infectious hepatitis, or diabetes and inflamed gallbladders.[6] As pointed out in Mainland, *Elementary Medical Statistics*, pp. 117-22 (2d ed. 1964), a retrospective study can yield an association unrelated to cause and effect in one of two ways: 1) The person having the two events, here a woman using a spermicide and subsequently giving birth to a child with birth defects, or as in Berkson's study, a diabetic subsequently presenting with an inflamed gallbladder, is more apt to be carefully scrutinized for past medical history and thereby become part of a study sample; or 2) if the controls—*e.g.*, as here, women who have not given birth to babies with birth defects—are not representative of the same sample as that presented by the cases studied.

The race interaction, *i.e.*, an association among white women but not black, suggested to Oechsli that "the finding in the white group may have been a statistical fluke." Aa 16. On balance, he concluded that his data at most raised a "serious suspicion" requiring further research. Better designed and subsequent studies have never replicated Oechsli's data on heart abnormalities. Whether or not the statistical association was real or a fluke, however, the fact remains that Oechsli's data involved only an association between spermicides and heart abnormalities.[7]

The Smith study examined spermicides, among other agents, in an attempt to explain an increase in congenital limb deformities in Alberta, Canada between 1969 and 1971. Aa 27. This study likewise involved the same confounding spermicide,

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6 See Stoller *et al.*, *Incidence of Infective Hepatitis Followed by Down's Syndrome Nine Months Later*, Lancet 2:1221 (1965); Berkson, *Limitations of the Application of Fourfold Table Analysis to Hospital Data*, Biometrics Bulletin, 2:47 (1946).

7 As association is said to be statistically significant where the odds are 5% or less that the association found is due to chance.

PMA, as was involved in Oechsli. T 758; T 1300-01; T 1456. Smith concluded that "[n]o single causal relationship was established" (Aa 27) between any of the agents studied (including spermicides) and birth defects, and that his study was actually "reassuring" for continued use of spermicides. Aa 29.

Plaintiffs' experts disregarded Smith's own conclusion. Instead, they claimed that the study really found an association between spermicides and limb defects which emerged only after a large number of statistical manipulations performed by Smith, even though Smith himself recognized that such an association "might have been expected by chance." Aa 29; T 1300; Aa 57.

Eight epidemiological studies were published after August 1980. One of these, Jick (1981), was relied on by plaintiffs and the district court. Jick reported an association between spermicide use and limb reduction deformities, among other birth defects, but recognized problems with his study (among them inability to assure that the women studied had actually used spermicides for the relevant periods). He himself concluded that "the results should be considered tentative until confirmed by other data." Aa 47. Plaintiffs' primary expert, Dr. Buehler, agreed with that conclusion. T 357.

Jick's call for other data was quickly met. Within three years, four major epidemiological studies tested the validity of Jick's findings, using more precise exposure data. Subsequent to trial, two additional studies, one of which was introduced in draft form at trial, were published. Each of the studies highlighted the fact that, unlike the Jick study, exposure data (*i.e.*, whether a woman was using a spermicide at the time she became pregnant) were carefully ascertained. Each of them found no association between spermicide use and birth defects despite the fact that the CDC's study consisted of a sample "large enough to have virtually a 100 percent chance of detecting" such a relationship. Aa 64.

2) ***The Absorption Studies***

The only plausible mechanism of action postulated by plaintiff as to why spermicides might cause birth defects is that they may be absorbed through the vaginal wall and into a mother's circulatory system. T 243-44. There is, however, no objective evidence to support the theory that such absorption actually occurs. Four studies concerning absorption, two involving animals and two involving humans, were introduced into evidence. The human studies showed no such absorption. Nevertheless, the district court relied on the two animal studies and speculated that therefore such absorption occurred in humans as well as animals. This animal data, however, cannot substitute for proof of what happens in humans and even those animal studies do not establish teratogenesis in the animals.

Chvapil (1980) (Aa 98) concluded that slight amounts of non-ionic surfactants are absorbed through the vaginas of rats and rabbits, Aa 108-10, but as Buttar pointed out (1982) (Aa 112), the level of absorption was far below that considered to have teratogenic or any other pharmacological significance. Aa 116; T 1608; 47 Fed. Reg. 54,750, 54,751 (1982); T 1562-63.

3) ***The Animal Toxicity/Teratology Studies***

Seven other animal studies were introduced into evidence. Four of those studies examined whether spermicides evidenced systemic toxicity in animals. Three of them investigated the more specific issue of whether spermicides are teratogenic in animals.

Plaintiffs' causation experts and the district court purported to rely solely on a one-paragraph abstract of a single study involving rats by Buttar (1982) to support the hypothesis that spermicides penetrate through the vaginal wall. In the conclusion to his abstract, Buttar noted that the nonoxynol-9 "did not cause any discernible visceral or skeletal malformations" and that, therefore, a single dose of the substance is "embryolethal [*i.e.*, contraceptive] and fetocidal but *non-teratogenic in the rat at a dose approximately ten times higher than that*

recommended for controlling conception in women." Aa 156 (emphasis added).

However, just as with the Smith study, plaintiffs' experts chose to disregard the scientist's own conclusions based on data from his study. Instead, relying on the subsidiary finding that spermicides are embryolethal in rats at mega-doses, they conjectured this could also indicate they *might* be teratogenic. Even so, Dr. Buehler admitted that he did not "know what [Buttar's] embryolethality causation was." T 348.

D. Plaintiffs' Theories of Liability

Obviously the FDA sought to investigate far in advance of the trial in the District Court the "possibility" that spermicides "might cause" birth defects and to that end in 1983 requested its Standing Committee consisting of outstanding independent experts in the field of contraception and epidemiology to review this issue, including all of the studies before the District Court. 48 Fed. Reg. 51,534 (1983). This Committee concluded that there was no justification to warn actual or potential users of vaginal spermicides of a possibility of birth defects in event of a method failure and that no warning should accompany the product other than the statement "if vaginal irritation occurs and continues, contact your physician."

1) *Causation*

Dr. Buehler's subjective "belief" was that Katie Wells' limb defects had two distinct etiologies, T 298, and were caused by a vascular disruption attributable to spermicide. T 242-43; T 217; T 327. This hypothesis is pure speculation unsupported by any objective evidence.

Dr. Buehler claimed to rely on scientific literature to support two premises critical to his hypothesis: (1) that non-ionic surfactants are absorbed through the vagina into the mother's circulatory system and from there into the fetal circulatory system; and (2) his unconfirmed speculation that once in the fetal circulatory system, spermicides cause irritation and damage to the vascular supply, possibly by causing a blood clot which could result in a limb deficiency. T 243-44. In support of

the first premise, Dr. Buehler cited the animal absorption of Chvapil and Buttar. T 316-17. As discussed above, even if accepted at full face value, these studies do not support this theory. With respect to the second premise, namely that the pharmacologic properties of non-ionic surfactants irritate the blood supply or a blood vessel and cause clotting, Dr. Buehler himself conceded he knew of no objective scientific evidence supporting it. T 243.

Finally, Dr. Buehler relied "strongly" on the study by Buttar, which he asserted showed embryolethality in rats. T 268-69. He testified that he would have liked to see other animal studies using different genetic strains (T 335-36), and when shown such studies, had no credible explanation for their findings. These studies, which followed the FDA protocol, showed no teratogenicity or even embryolethality. *Id.*; T 391.

Dr. Buehler arrived at his opinion on causation to "a reasonable degree of medical certainty" by purporting to use the doctrine in medicine known as the diagnosis of exclusion. This doctrine allows a scientist to conclude that a particular agent is the cause of a condition by ruling out all other possible causative factors except the one under consideration. As a matter of basic science and mathematics, however, this doctrine—the diagnosis of exclusion—is inapplicable here. Dr. Buehler himself admitted that the etiology of 60% to 65% of birth defects is unknown. T 405-06. Thus, the failure to identify other possible external agents besides Ortho-Gynol is not sufficient to pinpoint it as the culprit. Moreover, despite his purported reliance on "absence of other causation," he conceded he could not "rule out" amniotic banding as a cause of the hand deformity. T 232.

Ortho's experts, an epidemiologist, Dr. Stolley, and an embryologist, Dr. Brent, pointed out the obvious fact that the existing medical literature simply provides no indication, let alone proof, that vaginal spermicides cause limb defects.

The embryologist expressed the opinion that Katie Wells' malformations were most likely the product of amniotic banding. As noted, the trial court found that scientific literature on

the claimed association between spermicides and birth defects was, at best, "inconclusive." Re 180. Because of the certainty with which Dr. Brent expressed his opinion, as well as the "bias" which the trial court believed both he and Dr. Stolley had exhibited, however, the trial court ruled that their opinions could not be credited. Re 162, 176-77. On the other hand, because the trial court found all of plaintiffs' experts save one to be "credible," and because the studies did not "rule out all possibility" that spermicides "might" cause birth defects, he found for plaintiffs. Re 107, 180.

2) ***Failure to Warn***

As noted, the trial court found that vaginal spermicides "might" cause limb defects, and found plaintiffs' experts to be "credible." Because these "credible" experts gave their opinion to "a reasonable degree of medical certainty" that the vaginal spermicide caused the limb defects in this particular plaintiff, the trial court not only found that they were in fact caused by the spermicide but that Ortho was negligent for failure to warn in its labeling of this possibility as soon as there was a " 'hint' of a possibility."

To summarize, the trial court ruled in favor of the side whose experts he liked on this complicated scientific issue and the appeals court held that because this was a "classic battle of experts," the trial court was entitled to use this subjective selection process as a rationale for reaching this result. If trials are in fact supposed to be a search for the truth, this irrational decision-making process and the ensuing appellate review process simply cannot stand.[8] It goes without saying that makers of mass produced products cannot be expected to continue marketing those products in the face of such irrational and expensive condemnations by the judiciary.

8 This precise issue was addressed by the "Tort Policy Working Group," a committee formed by the United States Attorney General in 1985, which found that the lower courts have abrogated their responsibility in complex "scientific" tort cases. The committee recognized that there is a pervasive problem in these cases of improper causation findings based on invalid medical and scientific testimony. *See*, "Report of the Tort Policy Working Group on the Causes, Extent and

(*cont'd on next page*)

THE REASONS FOR GRANTING THE WRIT

I. THE ELEVENTH CIRCUIT'S STANDARD OF APPELLATE REVIEW IS INADEQUATE TO INSURE THE INTEGRITY OF THE FACT-FINDING PROCESS IN CASES WHERE LIABILITY HINGES ON COMPLEX SCIENTIFIC TESTIMONY

This case presents an issue of critical importance: clarification of the proper standard of appellate review in cases based upon complex scientific data and conflicting scientific expert testimony. The Eleventh Circuit enunciated a new standard of review, purportedly based on *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 105 S. Ct. 545 (1984). This standard not only conflicts with other circuits' standards, but also contravenes the standard articulated by this Court in *Anderson v. City of Bessemer City*, 470 U.S. 564, 105 S. Ct. 1504 (1985). The panel's new standard for "scientific" cases improperly insulates the district court's findings from effective appellate review and dramatically increases the probability of unjust results in cases where the truth requires reliance on technical and scientific evidence capable of objective evaluation. The decision of the Eleventh Circuit in *Wells* highlights the crucial need for this Court to clarify the proper standard of appellate review for the ever-increasing number of cases which must be determined by evaluation of complex scientific or technical data.

A. The Eleventh Circuit's Decision Creates a New and Impermissible Standard of Appellate Review For "Scientific" Cases

This Court's standard of review in *Anderson v. City of Bessemer City*, was misapprehended and misapplied in this case by the Eleventh Circuit. The appellate court is required under Fed. R. Civ. P. 52(a) to determine "[i]f the district court's

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Policy Implications of the Current Crisis in Insurance Availability and Affordability," February 1986; *see, infra*, pp. 22-24.

account of the evidence is plausible *in light of the record viewed in its entirety . . .*" *Anderson*, 105 S. Ct. at 1512 (emphasis added). However, in the *Wells* case, the Eleventh Circuit in effect established a new standard of review for scientific cases. It narrowed the scope of its review to the oral testimony of the plaintiffs' experts (including their interpretations of the "inconclusive" scientific studies they relied on), without evaluating the plausibility of that testimony in light of the scientific studies admitted into evidence.

The panel's failure to comply with *Anderson*'s command to review the record in its entirety is well evident throughout its opinion. For example, rather than independently reviewing or analyzing the four principal studies relied upon by plaintiffs and plaintiffs' experts, the Court merely listed the four epidemiological sources in a footnote,[9] and relied on *plaintiffs' expert's* characterization of their contents. *Wells*, 788 F.2d at 744 n.6. That hardly constitutes an evaluation (or even a basis for an evaluation) of the sufficiency of the evidence.

In addition, the panel did not evaluate the district court's account of the evidence in light of the unanimous conclusions of two FDA review panels and the many scientific studies in evidence (including those by researchers with the NIH, CDC and Harvard University) finding no credible scientific evidence of any association between this type of spermicide and birth defects. Nor did the panel explain how Dr. Buehler's opinions could be "highly credible" despite his conceded failure to read a majority of the relevant scientific studies, much less account for their findings. T 366; T 379; T 389; T 397; T 399-402; T 391-92; T 394. *Compare Brown v. Syntex Laboratories, Inc.*, 755 F.2d 668, 673 (8th Cir. 1985); *Wisconsin v. Weinberger*, 745 F.2d 412, 422 (7th Cir. 1984). Indeed, the panel went beyond plaintiffs' experts' testimony when it found that: "Plaintiffs noted various studies relative to absorption suggesting that absorption of the spermicide by the mother produced vascular disruption in the fetus that led to the birth defects." *Wells*, 788 F.2d at 744-45 (footnote omitted). This is incorrect. It is

9 As noted above, Buttar's rat study is not an epidemiological work.

undisputed that only one of the plaintiffs' experts even testified that it was "possible" that spermicide could produce such a vascular disruption. T 543. Referring to it as "my opinion," Dr. Sutherland specifically stated that he knew of no study to support his view and had never "actually seen this specific written idea." T 554; T 627.

In proceeding to review the district court's findings of facts by focusing exclusively on the oral testimony of the plaintiffs' experts, and blindly accepting such testimony at face value, the panel disregarded this Court's admonition that a trial judge may not

> insulate his findings from review by denominating them credibility determinations, for factors other than demeanor and inflection go into the decision whether or not to believe a witness. Documents or objective evidence may contradict the witness' story; or the story itself may be so internally inconsistent or implausible on its face that a reasonable factfinder would not credit it. [*Anderson*, 105 S. Ct. at 1512-13].

Rather than comply with the broad-based review mandated by *Anderson*, the panel evidently determined that a different standard should be applied since this case involves complex scientific data and evaluation. The panel's decision to forego a fair and adequate review of all of the evidence and to accept blindly the plaintiffs' experts' oral evidence at face value was based on dicta from *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 105 S. Ct. 545 (1984). In *Ferebee*, the D.C. Circuit indicated that in any "battle of the experts" involving "complex and refractory causal issues . . . which stand at the frontier" of science, an appellate court should invariably sustain the trier of fact's choice of "the victor." The Court reasoned that:

> Judges, both trial and appellate, have no special competence to resolve the complex and refractory causal issues raised by the attempt to link low level exposure to toxic chemicals with human disease. On questions such as

> these, which stand at the frontier of current medical and epidemiological inquiry, *if experts are willing to testify* that such a link exists, it is for the jury to decide whether to credit such testimony. [*Id.* at 1534; emphasis added].

The panel interprets *Ferebee* to hold that in complex scientific cases appellate review is properly limited to the relatively mechanical task of ascertaining whether there is any expert testimony in the record which, if taken at face value, supports the trial court's decision.

The panel's decision to consider only the plaintiffs' experts' oral testimony, and its acceptance of their testimony at face value, led it to fail in its "unavoidable duty," *Dayton Board of Education v. Brinkman*, 443 U.S. 526, 534 n.8, *reh. denied*, 444 U.S. 887 (1979), to set aside factual determinations which, as here, are untenable in light of the record as a whole. Moreover, as discussed below, the panel's creation of this unique standard of review for cases involving complicated scientific data conflicts with the standard utilized by courts in other circuits as well as that mandated in *Anderson*.

B. The *Wells* Standard Improperly Insulates the District Court's Fact-Finding Methodology and Conflicts with Other Circuits and the *Anderson* Standard

In utilizing its new standard for review of cases involving complex scientific data, the panel failed to analyze the appropriateness of the district court's fact-finding methodology. Consistent with the mandate of *Anderson* and the practice of other Circuits, the panel had a duty to look behind the district court's finding of credibility of scientific testimony to determine whether "[d]ocuments or objective evidence may contradict the witness' story; or [whether] the [testimony] may be so internally inconsistent . . . that a reasonable factfinder would not credit it." *Anderson* 105 S. Ct. at 1512-13. A brief review of the testimony of only one of plaintiffs' experts highlights the type of flawed methodology utilized by the district court and impermissibly ignored by the panel.

For example, the panel noted Dr. Buehler's reliance on certain epidemiological studies, but failed to evaluate the appropriateness of this reliance, and thus never recognized that his analysis was literally meaningless. Dr. Buehler relied on several epidemiological studies, including (1) Oechsli (unpublished 1976) because it "indicated a question and possible relationship between spermicides and birth defects" (*Wells*, 788 F.2d at 744 n.6); (2) Smith (1977) because it "contained data suggesting an association between spermicides and limb deficiencies" (*id.*); and (3) Jick (1981) because it "raised a serious question about an association between spermicides and limb defects." *Id.*

The basic principles of epidemiology established in the record below, however, completely undermine Dr. Buehler's "analysis." An epidemiological study does not "suggest an association"; it either finds a statistical association or it does not. T 1357-58. Scientific data must, of course, be interpreted in accordance with scientific conventions. *Moultrie v. Martin*, 690 F.2d 1078, 1082 (4th Cir. 1982).[10] Dr. Buehler could not, therefore, produce any credible new insights or data with

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10 The Fourth Circuit in *Moultrie v. Martin* set forth the proper standard to be used in interpreting scientific or technical data in the courtroom. In a race discrimination case, for instance, when a litigant seeks to prove racial discrimination through the use of statistics, "he is borrowing the principles of another discipline, mathematics, and applying these principles to the law. *In borrowing from another discipline, a litigant cannot be selective in which principles are applied. He must employ a standard mathematical analysis. Any other requirement defies logic to the point of being unjust.*" *Moultrie*, 690 F.2d at 1082 (emphasis added); *accord* Loevinger, *Jurimetrics: Science in Law*, Scientists in the Legal System (W. Thomas ed. 1974) ("Scientists can best influence the adjudicatory process by working as scientists." "If scientists are to make a significant contribution . . . they must first produce relevant and significant scientific data and conclusions.").

As the Fourth Circuit indicated in *Moultrie*, the data utilized to create a prima facie claim of racial discrimination in a Title VII action must be statistically significant. Consequently, an expert could not, based on a disparity in the raw data that lacks statistical significance, nonetheless testify that those data "suggest" racial discrimination. Yet, that is precisely what Dr. Buehler did here.

respect to his reliance on the relevant epidemiology because he was not qualified to make an independent analysis of the scientific data contained in these epidemiological studies. Dr. Buehler himself conceded his professional incompetence in this area several times, explaining that "I'm not an epidemiologist. That's outside my expertise," T 352 and T 358, "I don't know how to figure [statistical significance]," T 353, and "I don't understand confidence levels. I never use them." T 358.

When all is said and done, the sole statistical or objective evidence on which the causation finding was based remains the race interaction statistical association found by Oechsli regarding heart abnormalities among children of white women as opposed to black women or women of both races combined. Statistical associations by definition cannot prove cause and effect relationships. Here, the sole association even found appears to be one of chance and not actually probative of the defect suffered. Accordingly, plaintiffs' experts themselves had to acknowledge the "well-known principle of epidemiology that for the results of a study to be considered valid they must be replicated." T 614; T 773-74; T 328-30. Moreover, plaintiffs' experts also had to concede that none of the studies they relied upon had ever been replicated, thereby precluding legitimate reliance on that association. *See*, *e.g.*, T 774. Thus, Dr. Buehler's analysis of the data, by his own terms, cannot be valid.[11]

In the final analysis, the panel's application of its new standard of review for scientific cases allowed it to sidestep these and other blatant methodological flaws that permeate the district court's factual findings. Relying on *Ferebee*, the panel reasoned that because "a cause-effect relationship need not be *clearly* established by animal or epidemiological studies before a doctor can testify that, in his opinion, such a relationship

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11 In a footnote, the panel acknowledged Ortho's argument on the undisputed scientific requirement of replication (*Wells*, 788 F.2d at 744 n.4), and then entirely ignored that critical principle in its review of the case.

exists," *Wells*, 788 F.2d at 745 (quoting *Ferebee*, 736 F.2d at 1535 [emphasis added]), a trier of fact may, therefore, reasonably find causation even if "the medical community might require more research and evidence before *conclusively* resolving the question." *Wells*, 788 F.2d at 745 (emphasis added). These truisms do not meet the issue in this case. Here the burden of proof is, or should be, the same as that used in the scientific community: does the objective evidence establish that a) it is more probable than not that this vaginal spermicide on occasion causes limb defects; and b) is it more probable than not that it did so here? This is undoubtedly why the law requires only that an opinion be expressed to a *reasonable* degree of medical certainty.

Thus, *Ferebee*'s purported distinction between "legal sufficiency" and "scientific certainty" (736 F.2d at 1536) is actually a mask for ignoring science. Science does not require certainty. Proof in law and proof in science dovetail. Both science and law seek to determine what *probably* occurred based on *all* of the reliable evidence. *See* Loevinger, *supra* at 22 (W. Thomas ed. 1974) ("Science is like law in that it is a mode of seeking agreement among different individuals with respect to certain [factual] questions. . . . The common elements in both have been an effort to be wholly rational, to organize and institutionalize the search for truthful data, and, above all, seek truthful data as the basis for judgments. Science can equally accept the basic principles of the legal system: to accept only rationally probative evidence and to examine all relevant evidence.").

Here the panel relied on *Ferebee*'s strawman distinction to rationalize legal liability where the scientific evidence is, at best, conjectural. As a factual matter, it is virtually impossible to prove that any substance taken by a pregnant woman does *not* cause birth defects, but where, as here, there is no plausible mechanism of action and no credible epidemiological data that the substance in issue does cause birth defects, that should end the inquiry.

The Eleventh Circuit sought to neutralize the lack of objective scientific evidence by explaining that the district court's "ultimate focus was *the birth defects suffered by Katie Wells*." *Wells*, 788 at 745 (quoting 615 F. Supp. at 292 [emphasis in the original]). Like the district court, the panel ignored a logical prerequisite in leaping to the "ultimate focus." Before it can be determined that a substance was the cause in fact of an individual's birth defects, it must be established as a general proposition that it can cause birth defects in the first place. The district court, however, found that the data relied on by the plaintiffs' experts on the question of causation in general only "indicated a possible link between spermicides and birth defects." *Wells*, 615 F. Supp. at 292. Therefore, it is logically impossible to find that this "possible" cause of birth defects was "more likely than not" the probable cause of the birth defects in this case.

In its reliance on *Ferebee*'s inherently untenable distinction between legal and scientific proof to justify the district court's failure to weigh in the balance anything but plaintiffs' experts' testimony, the panel ignored its duty to determine whether plaintiffs' experts utilized a "sound" methodology in reaching their conclusions. In thus aligning itself with the D.C. Circuit in *Ferebee*, the panel established a standard of review in "scientific" cases that directly conflicts with that of other circuits.[12] For example, in *Wisconsin v. Weinberger*, 745 F.2d

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12 Where, as here, a trier of fact has found an expert's data "inconclusive" and indicative of no more than a "possibility" of causation, as in this case, an expert's "demeanor" cannot serve as a surrogate for a finding of causation to a reasonable degree of medical certainty. If judicial proceedings are to be actual *fact* finding proceedings, scientific evidence cannot be ignored because of a fact-finder's preference or dislike of an expert's demeanor, tone and possible biases. As one court observed:

> [T]his Court was extremely impressed with the sincerity of Dr. Winsch, plaintiff's . . . expert witness. Dr. Winsch obviously thoroughly studied the various theories relating to the cause of MS and carefully explained to the Court the basis for his opinion. . . . *[A]s compelling as plaintiff's theory is, it remains an unproven theory only* and those physicians with more experience than Dr.

(*cont'd on next page*)

412, 422-24 (7th Cir. 1984), the Seventh Circuit reviewed the district court's fact-finding methodology, including an independent review of representative samples of highly technical, scientific evidence. On the basis of that review, the Court determined that the district court's finding in plaintiffs' favor was "clearly erroneous" because the scientific studies their experts had relied on were "generally unimpressive and cannot be deemed sufficiently significant." *Id.* at 424.

Similarly, in *Lima v. United States*, 708 F.2d 502, 506 (10th Cir. 1983), the Tenth Circuit conducted an independent review of the trial court's fact-finding methodology, including the data upon which experts relied. Upon that review, the Court upheld the trial court's finding that swine flu vaccine was a proximate cause or contributing factor of plaintiff's neurological disorder. In *Moultrie v. Martin*, 690 F.2d 1078 (4th Cir. 1982), the Fourth Circuit extensively reviewed and rejected the methodology used by the litigant where the litigant relied upon complex statistical and mathematical principles, and failed to apply these principles and data in a way consistent with the general principles of mathematics. *Id.* at 1082.

> Winsch in the relevant fields have not been able to conclude as he has, that the swine flu shot caused MS in any person. . . . There is, therefore, very little medical literature to support Dr. Winsch's opinion and the studies that are available cast some doubt on the viability of plaintiff's theory.

Hupp v. United States, 563 F. Supp. 25, 29 (S.D. Ohio 1982) (emphasis added); *See, also, New England Coalition on Nuclear Pollution v. NRC*, 582 F.2d 87, 100 (1st Cir. 1978) (An expert's credibility "is a function of logical analysis, credentials, data base, and other factors readily discernible to one who reads the record."); *Allan v. United States*, 588 F. Supp. 247, 416-43 (D. Utah 1984); *See, generally*, W. Gellhorn & C. Byse, *Administrative Law* 1056 (4th ed. 1960) ("Scientific questions . . . will not be decided upon the basis of the witnesses' behavior while testifying.").

C. This Case Presents an Urgent And Recurring Problem Which Threatens the Availability of Essential Goods to the Public

Today the legal system, if it is to fulfill its function in a complex society, must rely on objective evidence on scientific matters such as the safety and efficacy of drugs, *United States v. Rutherford*, 442 U.S. 544, 555 (1979), the dangers presented by chemicals in the workplace, *American Petroleum Inst. v. OSHA*, 581 F.2d 493 (5th Cir. 1978), *aff'd sub nom. Industrial Union Dep't v. American Petroleum Inst.*, 448 U.S. 607 (1980), and the safety requirements of nuclear power plants. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984). Both in the context of private litigation and in judicial review of administrative action, courts now deal with scientific issues of profound significance. *See* Tribe, *Legal Framework for the Assessment and Control of Technology*, 9 Minerva 243 (1973); *Katz, The Function of Tort Liability in Technology Assessment*, 38 Cin. L. Rev. 587 (1969).

Because erroneous decisions can have profound social consequences, in addition to their injustice, judges and legal scholars have continually sought to structure the courts' fact-finding methodology, *see, e.g., Symposium on Science and the Rules of Legal Procedure*, 101 F.R.D. 599 (1983). The fact-finding process must be structured to cope with "the anomaly of asking a lay judge or jury to resolve a dispute between experts on a subject about which they know nothing other than what the experts have told them." Bereano, *Courts as Institutions for Assessing Technology*, Scientists in the Legal System 88 (W. Thomas ed. 1974).

The judiciary's lack of a structured fact-finding methodology for "scientific" cases has critically undermined its ability to deal with complex medical and scientific concepts in a principled and rational manner. The ever-increasing "reliance of judges and juries on noncredible scientific or medical testimony, studies or opinions" has been thoroughly examined

by the "Tort Policy Working Group,"[13] in a report issued February 1986. "Report of the Tort Policy Working Group on the Causes, Extent and Policy Implications of the Current Crisis in Insurance Availability and Affordability," February 1986, ("the Report"), p. 35. The committee found that

> "[o]ne of the most pernicious developments in tort law has been the extent to which causation findings are based on fringe scientific or medical opinions well outside the mainstream of accepted scientific or medical beliefs. Increasingly, jurors are asked to make difficult decisions about highly complicated issues of science and medicine. *Unfortunately, the personality and demeanor of expert witnesses often may be more critical in making such determinations than decades of evolving scientific and medical investigation and thought.* [*Id.* at 62; emphasis added].

The Report further highlights the fact that, as in this case, the courts' use of scientifically and medically invalid evidence "has resulted in findings of causation which simply cannot be justified or understood from the standpoint of the current state of credible scientific and medical knowledge." *Id.* at 32. Moreover, the committee found that this dangerous development in tort law has produced a "deep and growing cynicism" for the judiciary's ability to properly resolve cases involving difficult scientific or technical concepts.[14] *Id.* at 35. The committee stated that

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13 The "Tort Policy Working Group" is a committee set up by the United States Attorney General in 1985 and composed of representatives from ten federal agencies and the White House. The primary representatives are from the Department of Justice, Department of Commerce and the Small Businesses Administration.

14 The committee made several recommendations for solving the problems created by the lack of an effective fact-finding methodology for complex scientific cases:

1) The courts should become "more aggressive in determining the credibility of scientific and medical evidence and opinions," *id.* at 35; and

(*cont'd on next page*)

> This problem has resulted in the growing perception that the tort system often is wholly arbitrary in allocating liability in cases involving difficult issues of science and medicine. This is a particularly problematic situation in toxic tort and drug liability cases. [*Id.* at 62]

The threat of the imposition of liability on a nonfactual basis, such as that relied upon in this case, is felt most acutely in the health and pharmaceutical field, where causation is necessarily complex and often uncertain, *see* Lewin, *Pharmaceutical Companies Are The Hardest Hit*, N.Y. Times, Mar. 10, 1985, § 3, at 1, while some risks are recognized to be unavoidable as a matter of law. See comments j and k to *Restatement (Second) of Torts*. For example, pharmaceutical manufacturers have ceased making DPT or whooping cough vaccines and IUD's as a direct result of the danger of excessive and unpredictable products liability verdicts. *See* Lewin, *supra*; *see also* Lewin, *Contraceptive Suits a Concern*, N.Y. Times, June 10, 1986, at D2 (suits for rare, unavoidable side effects of IUD prompted manufacturer to cease production; Planned Parenthood concerned that this reduces women's access to effective birth control; *Wells v. Ortho* and possible withdrawal of spermicide also cited with concern); Wash. Post, Dec. 20, 1984 § 1, at A18 (shortage of DPT vaccine occurs, since only one distributor of DPT vaccines remains because two others have ceased either production or distribution due to damages suits).

This Court should grant the petition for certiorari to address the issues concerning the interrelationship between science and law, and to clarify the appropriate standard of review in cases hinging on complex scientific data. The Eleventh Circuit's

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2) *Greater deference must be paid to government agencies* and certain private institutions *that have devoted decades of attention and millions of dollars to researching and trying to assess the value of medical and scientific developments.* Where such agencies and institutions have determined that particular products, services or techniques are safe or socially beneficial, courts should tread very carefully in overruling those judgments through the vehicle of tort law. *Id.* at 63 (emphasis added).

unique standard must be rejected by this Court. It serves to defeat the intrinsic purpose of appellate review because it greatly increases the probability that the result in a "scientific" case like *Wells* will not "reflect the truth and the right of the case," *Armstrong Cork Co. v. World Carpets, Inc.*, 597 F.2d 496 (5th Cir.), *cert. denied*, 444 U.S. 932 (1979).

CONCLUSION

For the reasons set forth above, the petition for a Writ of Certiorari should be granted.

Respectfully submitted,

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